



Attorney's Docket No. EPC-148-C1

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

08/359937

Anticipated Classification of this application:

Class 424 Subclass

Serial Number: 0 8 / 065,676

PRIOR APPLICATION

Examiner: G. Kishore

Art Unit: 1502

#10/C
2/18/96

Box FWC

Commissioner of Patents and Trademarks

Washington, D.C. 20231

FILE WRAPPER CONTINUING APPLICATION (FWC) TRANSMITTAL

WARNING: This form cannot be used where the parent case may not be abandoned since the filing of a request under the FWC procedure "will be considered to be a request to expressly abandon the prior application as of the filing date granted to the continuing application." 37 CFR 1.62(g).

WARNING: This procedure can only be used for a pending application prior to payment of the issue fee. 37 CFR 1.62(a) except if the parent application was withdrawn under 37 CFR 1.313(b)(5) "to permit consideration of an information disclosure statement under 1.97 in a continuing application." See Notice of January 9, 1992 (1135 O.G. 13-25 at 21).

WARNING: The filing of an application at the United States stage of an international application requires an oath or declaration. 37 CFR 1.61(a)(4).

WARNING: The claims of this new application may be finally rejected in the first Office action where all claims of the new application are drawn to the same invention claimed in the earlier application and would have been properly finally rejected on the grounds or art of record in the next Office action if they had been entered in the earlier application. MPEP § 706.07(b).

WARNING: An application under 37 CFR 1.62 is filed by making changes by amendment to the prior application, 37 CFR 1.62(a), and not by filing a new application. 37 CFR 1.62(e).

WARNING: Filing under 37 CFR 1.62 is permitted only if filed by the same or less than all the inventors named in the prior application. 37 CFR 1.62(a).

CERTIFICATION UNDER 37 CFR 1.10

I hereby certify that this FWC Transmittal and the documents referred to as attached therein are being deposited with the United States Postal Service on this date December 20, 1994 in an envelope as "Express Mail Post Office to Addressee" mailing Label Number 4B655980391US addressed to the: Commissioner of Patents and Trademarks, Washington, D.C. 20231.

Mark J. Laffey

(Type or print name of person mailing paper)

(Signature of person mailing paper)

NOTE: Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. (37 CFR 1.10(b)).

WARNING: Certificate of mailing (first class) or facsimile transmission procedures of 37 CFR 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.

(FWC [4-2]—page 1 of 11)

Patent to G.P.

C

This is a request for a filing under the file wrapper continuing application procedure, 37 CFR 1.62, for a

- ☒ continuation
- ☐ divisional
- ☐ continuation-in-part (for oath or declaration see III below)
attached is an amendment for added subject matter
- ☐ continuing application to permit consideration of an information disclosure statement under 37 CFR 1.97.

NOTE: The filing date under 37 CFR 1.62(a) is "... the date on which a request is filed for an application ... including identification of the Serial Number, filing date and applicant's name of the prior application". The prior application under 37 CFR 1.62(a) must be "... a prior complete application." According to 37 CFR 1.51(a) a prior complete application comprises: (1) a specification, including a claim or claims; (2) a declaration; (3) drawings; when necessary; and (4) the prescribed filing fee. Accordingly, as presently worded, 37 CFR 1.62(f) does not permit the FWC procedure to be used where the prior application is pending but only the processing and retention fee required by 37 CFR 1.21(f) is paid.

PARTICULARS OF PRIOR APPLICATION

- This application is a file wrapper continuing application of USSN 08/065,676
- A. filed May 21, 1993; which is a continuation-in-part of USSN 07/842,351 filed March 24, 1992; which is the U.S. National Stage of PCT/GB90/01676 filed November 1, 1990; which corresponds to UK 8924935.3 filed November 4, 1989
 - B. Title (as originally filed) "SMALL PARTICLE COMPOSITIONS FOR INTRANASAL DRUG DELIVERY." and as last amended) N/A
 - C. Name of applicant(s) (as originally filed and as last amended) and current correspondence address of applicant(s)

SEE FOLLOWING PAGE FOR THIS INFORMATION

1. FULL NAME OF INVENTOR	FAMILY NAME <u>ILLUM</u>	FIRST GIVEN NAME <u>Lisbeth</u> 100	SECOND GIVEN NAME
RESIDENCE & CITIZENSHIP	CITY <u>The Park</u>	STATE OR FOREIGN COUNTRY ENGLAND 382	COUNTRY OF CITIZENSHIP DENMARK
POST OFFICE ADDRESS	POST OFFICE ADDRESS 19 Cavendish Crescent North,	CITY The Park, Nottingham	STATE & ZIP CODE/COUNTRY ENGLAND NG7 1BA
2. FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
3. FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY

☐ Continued on added page for Inventor's Data

The above identified application, in which no payment of issue fee, abandonment of (other than where the above identified application was abandoned under 37 CFR 1.313(b)(5) to permit consideration of an information disclosure statement under 37 CFR 1.97), or termination of proceedings has occurred, is hereby expressly abandoned as of the filing date of this new application. Please use all the contents of the prior application file wrapper, including the drawings, as the basic papers for the new application.

It is understood that secrecy under 35 U.S.C 122 is hereby waived to the extent that if information or access is available to any one of the applications in the file wrapper of a 37 CFR 1.62 application, be it either this application or a prior application in the same file wrapper, the PTO may provide similar information or access to all the other applications in the same file wrapper.

II. Inventorship statement

NOTE: "If the continuation, continuation-in-part, or divisional application is filed by less than all the inventors named in the prior application a statement must accompany the application when filed requesting deletion of the names of the person or persons who are not inventors of the invention being claimed in the continuation, continuation-in-part, or divisional application." 37 CFR 1.62(a) [emphasis added].

NOTE: "In the case of a continuation-in-part application which adds and claims additional disclosure by amendment, an oath or declaration as required by § 1.63 must be filed. In those situations where a new oath or declaration is required due to additional subject matter being claimed, additional inventors may be named in the continuing application. In a continuation or divisional application which discloses and claims only subject matter disclosed in a prior application, no additional oath or declaration is required and the application must name as inventors the same or less than all the inventors in the prior application." 37 CFR 1.60(c).

(complete applicable item (a), (b) and/or (c) below)

- (a) ☒ This application discloses and claims only subject matter disclosed in the prior application whose particulars are set out above and the inventor(s) in this application are
- ☒ the same
- ☐ less than those named in the prior application and it is requested that the following inventor(s) identified above for the prior application be deleted:

(type name(s) of inventor(s) to be deleted)

- (b) ☐ This application discloses and claims additional disclosure by amendment and a new declaration or oath is being filed. With respect to the prior application whose particulars are set out above the inventor(s) in this application are
- ☐ the same
- ☐ add the following additional inventor(s)

(type name of inventor(s) to be added)

- (c) The inventorship for all the claims in this application is
- ☒ the same
 - ☐ not the same, and an explanation, including the ownership of the various claims at the time the last claimed invention was made, is submitted.

III. Declaration or oath

A. Continuation or divisional

- ☒ none required

B. Continuation-in-part

- ☐ attached

executed by (check all applicable items)

- ☐ inventor(s).
- ☐ legal representative of inventor(s). 37 CFR 1.42 or 1.43.
- ☐ joint inventor or person showing a proprietary interest for inventor who refused to sign or cannot be reached. 37 CFR 1.47;
- ☐ This is the petition required by 37 CFR 1.47 and the statement required by 37 CFR 1.47 is also attached. (See item VIII below for fee.)
- ☐ not attached
 - ☐ Application is made by a person authorized under 37 CFR 1.41(c) on behalf of all of the above named applicant(s). (The declaration or oath, along with the surcharge required by 37 CFR 1.16(e) can be filed subsequently.)
 - ☐ Attached is a showing that the filing is authorized. (Not required unless called into question. 37 CFR 1.41(d).)

IV. Identification of Claims for Further Prosecution

WARNING: "The claims of a new application may be finally rejected in the first Office action in those situations where (1) the new application is a continuing application of, or a substitute for, an earlier application, and (2) all the claims of the new application (a) are drawn to the same invention claimed in the earlier application, and (b) would have been properly finally rejected on the grounds of art of record in the next Office action if they had been entered in the earlier application." MPEP, § 706.07(b).

- ☒ The fees to be charged are to be based on the number of claims remaining as a result of the:
 - ☐ attached preliminary amendment.
 - ☐ the unentered amendment filed under 37 CFR 1.116 in the prior application, which is now repeated.
 - ☒ the claims as on file in the prior application.

V. Fee Calculation (37 CFR 1.16)

NOTE: The filing fee for a continuation, continuation-in-part, or divisional application is based on the number of claims remaining in the application after entry of any preliminary amendment and entry of any amendments under 37 CFR 1.116 unentered in the prior application which is requested to be entered in this FWC application. 37 CFR 1.62.

CLAIMS FOR FEE CALCULATION

Number Filed	Number Extra	Rate	Basic Fee 37 CFR 1.16(a) \$710.00 \$730.00
Total Claims (37 CFR 1.16(c) 14-20 =	0	X \$ 22.00	0
Independent Claims (37 CFR 1.16(b)) 1-3 =	0	X \$ 74.00	0
Multiple dependent claim(s), if any (37 CFR 1.16(d))		+ \$230.00	0

☐ The fee for extra claims is not being paid at this time.

Filing fee calculation \$ 730.00

NOTE: If the fees for extra claims are not paid on filing they must be paid or the claims cancelled by amendment, prior to the expiration of the time period set for response by the Patent and Trademark Office in any notice of fee deficiency. 37 CFR 1.16(d).

VI. Petition for Suspension of Prosecution for the Time Necessary to File an Amendment

NOTE: Where it is possible that the claims on file will give rise to a first action final for this continuation application and for some reason an amendment cannot be filed promptly (e.g., experimental data is being gathered) it may be desirable to file a petition for suspension of prosecution for the time necessary.

(check the next item, if applicable)

☒ There is provided herewith a Petition to Suspend Prosecution for the time Necessary to File an Amendment (New Application Filed Concurrently).

VII. Small Entity Statement

☐ A verified statement that this is a filing by a small entity is attached.

☒ The small entity statement was filed in the parent application Serial No. 08 / 065,676 which parent application was filed on May 21, 1993 and this status is still proper and its benefit under 37 CFR 1.28(a) is hereby claimed.

Reduced filing fee calculation (50% of above) \$ 365.00

NOTE: 37 CFR 1.28(a) states "Status as a small entity must be specifically established by a verified statement filed in each application or patent in which the status is available and desired, except those applications filed under § 1.60 or § 1.62 of this part where the status as a small entity has been established in a parent application and is still proper."

The last sentence of 37 CFR 1.28(a) states: "Applications filed under § 1.60 or § 1.62 of this part must include a reference to a verified statement in a parent application if status as a small entity is still proper and desired."

Any excess of the full fee paid will be refunded if a verified statement and a refund request are filed within 2 months of the date of timely payment of a full fee then the excess fee paid will be refunded on request. 37 CFR 1.28(a).

VIII. Fee Payment Being Made at This Time

Not attached

- ☐ No filing fee is submitted. (This and the surcharge required by 37 CFR 1.16(e) can be paid subsequently.)

Attached

- ☒ filing fee \$ 365.00
- ☐ recording assignment (\$40.00; 37 CFR 1.21(h)). For payment of fee see item XIV below.
- ☐ petition fee for filing by other than all the inventors or person not the inventor where inventor refused to sign or cannot be reached (\$130.00; 37 CFR 1.47 and 1.17(h)) \$ _____
- ☐ processing and retention fee (\$130.00; 37 CFR 1.53(d) and 1.21(l)) \$ _____

NOTE: 37 CFR 1.21(l) establishes a fee for processing and retaining any application which is abandoned for failing to complete the application pursuant to 37 CFR 1.53(d) and this, as well as the changes to 37 CFR 1.53 and 1.78 indicate that in order to obtain the benefit of a prior U.S. application, either the basic filing fee must be timely paid or the processing and retention fee in § 1.21(l) must be paid within 1 year from the notification under § 1.53(d).

Total fees enclosed \$ 365.00

IX. Method of Payment of Fees

- ☒ Attached is check in the amount of \$ 365.00
- ☐ Charge Account No. _____ in the amount of \$ _____
- ☐ A duplicate of this request is attached.

NOTE: Fees should be itemized in such a manner that it is clear for which purpose the fees are paid. 37 CFR 1.22(b).

X. Authorization to Charge Additional Fees

WARNING: If no fee payment is made at this time this item should not be completed.

WARNING: Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges if extra claim charges are authorized.

- ☒ The Commissioner is hereby authorized to charge the following additional fees which may be required by this paper and during the entire pendency of this application to Account No. 12-2147:
- ☒ 37 CFR 1.16(a), (f) or (g) (filing fees)
- ☒ 37 CFR 1.16(b), (c) and (d) (presentation of extra claims)

NOTE: Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 CFR 1.16(d)) it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.

- ☐ 37 CFR 1.16(e) (surcharge for filing the basic filing fee and/or declaration on a date later than the filing date of the application)
- ☒ 37 CFR 1.17 (application processing fees)

WARNING: While 37 CFR 1.17(a), (b), (c) and (d) deal with extensions of time under § 1.136(a) this authorization should be made only with the knowledge that: "Submission of the appropriate extension fee under 37 CFR 1.136(a) is to no avail unless a request or petition for extension is filed" (Emphasis added). Notice of November 5, 1985 (1060 O.G. 27).

- ☐ 37 CFR 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 CFR 1.311(b))

NOTE: Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the Notice of Allowance, 37 CFR 1.311(b).

From the wording of 37 CFR 1.28(b): (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity. Notification of any change of status resulting in loss of entitlement to small entity status must be filed in the application prior to, or at the time of, paying the issue fee. 37 CFR 1.28(b).

XI. Instructions as to Overpayment

- ☒ Credit Account No. 12-2147
- ☐ Refund

XII. Priority—35 U.S.C. 119

- ☒ Priority of application Serial No. 0 / 8924935.3 filed on November 4, 1989 in England is claimed under 35 U.S.C. 119. (country)
- ☒ The certified copy has been filed on March 24, 1992 in prior U.S. application Serial No. 07 / 842,351, which prior application was filed on March 24, 1992
- ☐ certified copy will follow

XIII. Relate Back—35 U.S.C. 120

- ☒ Amend the specification by inserting before the first line the sentence:

"This is a

- ☒ continuation
- ☐ divisional
- ☐ continuation-in-part

of copending application(s)

- ☒ Serial Number 08 / 065,676 filed on May 21, 1993
- ☐ International Application _____ filed on _____ and which designated the U.S."

NOTE: The proper reference to a prior filed PCT application which entered the U.S. national phase is the U.S. serial number and the filing date of the PCT application which designated the U.S.

XIV. Assignment

- ☒ The prior application is assigned of record to DANBIOSYST UK LIMITED

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☐ An assignment of the invention to _____

is attached. A separate ☐ "COVER SHEET FOR ASSIGNMENT (DOCUMENT) ACCOMPANYING NEW PATENT APPLICATION" or ☐ FORM PTO 1595 is also attached.

NOTE: "If an assignment is submitted with a new application, send two separate letters - one for the application and one for the assignment." Notice of May 4, 1990 (1114 O.G. 77-78).

XV. Power of Attorney

The power of attorney in the prior application is to

Anthony M. Lorusso et al

25,059

(Attorney)

(Reg. No.)

- a. ☐ The power appears in the original papers in the prior application.
- b. ☒ The power does not appear in the original papers, but was filed on July 9, 1993
- c. ☐ A new power has been executed and is attached.
- d. ☒ Address all future communications to:

Anthony M. Lorusso

25,059

(Name)

(Reg. No.)

LORUSSO & LOUD

(Address)

440 Commercial St., Boston, MA 02109 (617)227-0700

(Tel. No.)

(Item d may only be completed by applicant, or attorney or agent of record.)

XVI. Maintenance of Copendency of Prior Application

(This item must be completed and the necessary papers filed in the prior application if the period set in the prior application has run.)

- ☒ A petition, fee and response has been filed to extend the term in the pending prior application until December 20, 1994.

NOTE: The PTO finds it useful if a copy of the petition filed in the prior application extending the term for response is filed with the papers constituting the filing of the continuation application. Notice of November 5, 1985 (1060 O.G. 27).

- ☒ A copy of the petition for extension of time in the prior application is attached.

XVII. Conditional Petitions for Extension of Time in Prior Application

(complete this item and file conditional petition in prior application if previous item not applicable)

- ☐ A conditional petition for extension of time is being filed in the pending prior application

NOTE: The PTO finds it useful if a copy of the petition filed in the prior application extending the term for response is filed with the papers constituting the filing of the continuation application. Notice of November 5, 1985 (1060 O.G. 27).

- ☐ A copy of the conditional petition for extension of time in the prior application is attached.

XVIII. Abandonment of Prior Application

- ☒ Please abandon the prior application at a time while the prior application is pending or when the petition for extension of time or to revive in that application is granted and when this application is granted a filing date so as to make this application copending with said prior application. At the same time please add the words "now abandoned" to the amendment to the specification set forth in XIII above.

NOTE: According to the Notice of May 13, 1983 (103 TMOG 6-7), the filing of a continuation or continuation-in-part application is a proper response with respect to a petition for extension of time or a petition to revive and should include the express abandonment of the prior application conditioned upon the granting of the petition and the granting of a filing date to the continuing application.

NOTE: "A registered attorney or agent acting under the provisions of § 1.34(a), or of record, may also expressly abandon a prior application as of the filing date granted to a continuing application when filing such a continuing application." 37 CFR 1.138.

XIX. Information Disclosure Statement

- ☐ Submitted herewith is an Information Disclosure Statement.

XX. Assignee Certification

WARNING: When an assignee files a continuation or divisional application (under 37 CFR 1.53, 1.60 or 1.62), reference may be made to a statement filed under 37 CFR 3.73(b) in the parent application or a copy of that statement may be filed. A newly executed statement under 37 CFR 3.73(b) must be filed when a continuation-in-part application is filed by an assignee. Notice of April 30, 1993, 1150 O.G. 62-64.

(complete the following if the assignee is signing below)

- ☐ This is a ☐ continuation ☐ divisional application and the statement under 37 CFR 3.73(b)
- ☐ has been filed in the parent application.
- ☐ a copy of the previously filed statement in the parent application is attached.
- ☐ This is a continuation-in-part application and a "CERTIFICATE UNDER 37 CFR 3.73(b)" is attached.

(type or print name of person signing declaration)

Date

Signature

(P.O. Address of Signatory)

(if applicable)

Tel. No.: ()

Reg. No.:

- ☐ Inventor
- ☐ Assignee of complete interest
- ☐ Person authorized to sign on behalf of assignee
- ☐ Attorney or agent of record
- ☐ Filed under Rule 34(a)

(complete the following if applicable)

Danbiosyst UK Limited

(type name of assignee)

6 William Lee Bldg., Highfields Science Park,

(Address of assignee)

Nottingham NG7 2RQ, ENGLAND

(Title of person authorized to sign on behalf of assignee)

Assignment recorded in PTO on July 12, 1993

Reel 6719 Frame 0465-0466

- ☐ Plus ADDED PAGE FOR INVENTOR'S DATA FOR FWC FILING
- ☐ Plus ASSIGNMENT (DOCUMENT) COVER LETTER ACCOMPANYING NEW PATENT APPLICATION

SIGNATURE OF ATTORNEY

Anne E. Fitzpatrick

Reg. No.

37,132

Anne E. Fitzpatrick

(type or print name of attorney)

Tel. No.: ~~XXX~~ (617)227-0700

LORUSSO & LOUD

440 Commercial Street

(P.O. Address)

Boston, MA 02109